NIPTE

One voice for pharmaceutical quality®

The National Institute for Pharmaceutical Technology & Education

COURSE PROPOSAL/SPECIFICATION

COURSE NAME: Quality by Design (QbD) and Process Analytical Technology (PAT) for Biopharmaceuticals: Concepts and Applications in Development and Commercialization

DESCRIPTION: This course aims to clarify the key concepts that interplay in defining and implementing QbD and PAT towards development and manufacturing of biotech products. This will be achieved via a sequence of lectures and group work. Concepts discussed include: Critical Quality Attributes (CQA), Design Space, Risk Assessment, Process Characterization, Process Analytical Technology, Scale-up, and Technology Transfer. At the end of the course, the audience will be able to explain what these concepts mean, the role they play in QbD/PAT implementation and the interplays amongst them.

RATIONALE: Successful implementation of Quality by Design (QbD) and Process Analytical Technology (PAT) concepts requires that the concepts are put in place when the first activities around designing the product are initiated and then continue to be incorporated into the designing of the process that is used to make the product and other activities associated with the lifecycle of a pharmaceutical product. This course will allow the participants to better understand how their job responsibilities will evolve in the QbD/PAT paradigm, what is the big picture and the role they play in ensuring successful implementation of QbD/PAT.

TARGET AUDIENCE: Individuals that are involved in product and process development, regulatory, quality assurance and control and manufacturing of biotech therapeutics. Attendees from academia and regulatory agencies may also benefit depending on their areas of interest and level of experience.

DURATION: Two days.

PREREQUISITES: Basic understanding of GMP manufacturing and commercialization lifecycle of a biotech product

OBJECTIVES: At the completion of this course, the participant will be able to:

- Explain what the above mentioned concepts mean
- Define CQAs
- Explain the link between CQAs and Design Space
- Describe what would he/she need to do differently in their present job in the QbD paradigm
- Explain the role of PAT in QbD paradigm
- Discuss the challenges of implementing QbD
- Explain the role of Risk Assessment and where to go to find the appropriate tool
- Describe at a high level how QbD can be implemented for commercialization of biotech products

MATERIALS: A complete list of materials. This will include, but is not limited to:

- Participants' Handouts
- Room Visuals (Flip Chart or White Board w/Markers, etc.)
- Overheads and Projector
- Consumable Supplies (markers, envelopes, lab supplies, etc.)
- Course Evaluation forms
- Other Handouts

REFERENCE BOOKS:

- Quality by Design for Biopharmaceuticals: Perspectives and Case Studies, Ed. by A. S. Rathore and R. Mhatre, Wiley Interscience, 2009, New Jersey.
- Process Analytical Technology Applied in Biopharmaceutical Process
- Development and Manufacturing, Ed. C. Undey, D. Low and J. M. C. de Menezes, Taylor and Francis, Boca Raton, pp 179-200, 2011.

COURSE OUTLINE:

Day 1

9-10:30 AM	Introduction to QbD, CQA and TPP
10.30-11 AM	Discussion + Break
11AM-12:30PM	QbD Case Studies for Upstream and Downstream Process Development
12:30-1:30PM	Lunch
1-3PM:	Introduction to Multivariate Data Analysis (MVDA) and Case Studies
3-3:30PM	Break
3:30-5PM:	Design of Experiment and Application in QbD
5-5:30PM:	Discussion and Wrap-up of Day 1

Day 2

9-10:30AM	Introduction to Process Analytical Technology (PAT) and Case Studies
10:30-11AM	Break
11AM-12:15PM	Process Characterization and Process Validation
12:15-1PM	Lunch
1-2:15PM	Process Investigation & Troubleshooting
2:15-2:45PM	Break
2:45-4PM	QbD Case Study: "Critical Process Parameters for Preparation of Amphotericin B Liposomes"